REMARKS

Claims 21-40, 75 and 76 are currently pending and under consideration. Claims 21, 22, 30, 32, 33, 38, 40, and 75 have been amended to more particularly point out and distinctly claim the subject matter of the invention. The amendments made herein are for clarification purposes only and are not intended to narrow the scope of the claims. No new matter is added by these amendments, and they are believed to place the claims in condition for allowance. The subject matter of the claims, as amended, is fully supported in the specification and claims as originally filed. Following entry of the amendments made herein, claims 21-40, 75 and 76 will be pending in the instant application.

Claim Rejection Under 35 U.S.C. § 112, first paragraph

Claim 21 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner contends that no basis or support can be found in the present specification for the use of a "controlled release preparation" in claim 21.

In response, Applicants respectfully disagree and direct the Examiner to page 21, lines 21-24, wherein it is stated: "The proanthocyanidin polymeric composition can also be provided as a controlled release system (see, *e.g.*, Langer, 1990, *Science* 249: 1527-1533)." In addition, it is noted on page 65 of the application that the publications cited in the application are to be incorporated in their entirety. Accordingly, for example on page 1528, second column of *Langer*, it is stated that "Controlled release systems deliver a drug at a predetermined rate for a definite time period." and "...a controlled release preparation maintains the drug in the desired therapeutic range by a single administration....advantages of controlled release systems include..." Thus, Applicants point out that there is support in

the specification, as filed, for the use of a "controlled release preparation" in claim 21, and further direct the Examiner to the Langer article, a copy of which is herewith submitted as Exhibit A. In view of the foregoing, withdrawal of the rejection under section 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 21-40 and 75-76 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner proposes that claims 21 and 22 be amended to specify that the "therapeutically effective amount" is to treat secretory diarrhea. Without agreeing with the Examiner and merely to expedite prosecution, Applicants have amended claims 21 and 22 to recite "a pharmaceutical composition comprising from 0.1 to 100 mg/kg/day of an aqueous soluble proanthocyanidin polymer composition isolated from a Croton species or a Calophyllum species, said aqueous soluble proanthocyanidin polymer composition being in an amount effective to treat secretory diarrhea". Applicants submit that such amended recitation makes clear that it is the amount of the proanthocyandin polymer composition that is effective to treat secretory diarrhea. In view of the foregoing, Applicants respectfully request that this rejection under section 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner contends that claim 22 is confusing in the recitation of "comprising administering, via the oral route of administration, a non-human animal or human suffering from diarrhea." The Examiner states that addition of the term "to" before "a non-human" would be remedial. In addition, the Examiner alleges that the recitation in claim 22 of a pharmaceutical composition "comprising a therapeutically effective amount comprising 0.1 mg to 100mg/kg/day of" is confusing in that it is uncertain what else the therapeutic amount comprises, or its purpose.

In response, without agreeing with the Examiner and merely to expedite prosecution, Applicants have accordingly clarified claim 22 by adding the term "to" as proposed by the Examiner. Claim 22 has been further amended for clarification purposes and, as amended, is directed to "a pharmaceutical composition comprising from 0.1 to 100 mg/kg/day of an aqueous soluble proanthocyanidin polymer composition isolated from a Croton species or from a Calophyllum species, said aqueous soluble proanthocyanidin polymer composition being in an amount effective to treat secretory diarrhea and coated with an enteric coating." Thus, Applicants submit that the amended recitation makes clear that it is the proanthocyanidin polymer composition that is present in a therapeutically effective amount. In view of the foregoing, Applicants respectfully submit that this rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner contends that claims 21 and 22 are incorrect and inconsistent in the recitation of "0.1 mg." Further to the Examiner's recommendation, claims 21 and 22 have been amended for clarification purposes by deleting "mg" to recite "0.1 to 100mg/kg/day." In view of the foregoing, Applicants respectfully request that the rejection of claims 21 and 22 under 35 U.S.C. § 112, second paragraph, for this reason, be withdrawn.

The Examiner alleges that claim 40 lacks proper antecedent basis in claim 22 for the term "is given between 0.1 and 40 mg/kg per day of the proanthocyanidin polymer composition." The Examiner points out that claim 22 is directed to administration of a pharmaceutical composition "comprising a therapeutically effective amount comprising 0.1 mg to 100 mg/kg/day of an aqueous soluble proanthocyanidin polymer composition," which is allegedly ambiguous.

In response, without agreeing with the Examiner and merely to expedite prosecution, Applicants have amended claim 22 for clarification purposes and, as amended, claim 22 is directed to "a pharmaceutical composition comprising from 0.1 to 100 mg/kg/day of an aqueous soluble proanthocyanidin polymer composition isolated from a Croton species

or from a Calophyllum species, said aqueous soluble proanthocyanidin polymer composition being in an amount effective to treat secretory diarrhea and coated with an enteric coating." Dependent claim 40 has been amended to add the term "aqueous soluble." As amended, claim 40 which is dependent upon claim 22, is limited to "0.1 mg to 40 mg/kg/day of the aqueous soluble proanthocyanidin polymer composition." Applicants regard the amendments made herein to further clarify any alleged ambiguity in claim 22 and to provide sufficient antecedent basis for claim 40. Based on amendments made herein to claims 22 and 40, Applicants respectfully request that the rejection of claim 40 under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis be withdrawn.

The Examiner contends that claim 32 is confusing because of the recitation of "cancers and neoplasias." Applicants respectfully disagree; to expedite prosecution, Applicants have added the term "and" to claim 32 to more particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Applicants further submit that one of skill in the art can readily ascertain the meaning of the term "cancers and neoplasias," wherein the cancers and neoplasias are further limited to those of the gastrointestinal tract. In view of the foregoing, Applicants respectfully request that the rejection of claim 32 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Examiner contends that claim 38 fails to find clear antecedent basis in claim 22 on which it ultimately depends for the term "is delivered in animal feed." Without agreeing with the Examiner and to expedite prosecution, Applicants have amended claim 38 by replacing the word "delivered" with the word "administered." Claim 36 on which claim 38 is dependent, is dependent upon the method of claim 22. Claim 22 is directed to a method of treatment for secretory diarrhea said method comprising administering, via the oral route of administration, a pharmaceutical composition. Applicants point out that there is proper antecedent basis for the limitation of dependent claim 38 as hereby amended wherein, the pharmaceutical composition "is administered in animal feed." In view of the foregoing,

Applicants respectfully request that the rejection of claim 38 under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis be withdrawn.

The Examiner rejects claim 75 for failing to find clear antecedent basis in claim 22 for "the isolated proanthocyanidin polymer." Without agreeing with the Examiner and merely to expedite prosecution, Applicants have amended claim 75 by replacing the term "isolated" with the term "aqueous soluble." As amended, dependent claim 75 is directed to the method of claim 22, wherein "the aqueous soluble proanthocyanidin polymer composition is directly compressible." Claim 22 is directed to a pharmaceutical composition comprising 0.1 mg to 100 mg/kg/day of an aqueous soluble proanthocyanidin polymer composition. Applicants point out that amended claim 75 finds clear antecedent basis in claim 22 for the aqueous soluble proanthocyanidin polymer composition. In view of the foregoing, Applicants respectfully request that the rejection of claim 75 under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis be withdrawn.

Claim objected to Under 37 CFR 1.75(c)

The Examiner objects to claim 36 under 37 CFR 1.75(c), as being of improper dependent form for failing to limit the subject matter of a previous claim. Applicants respectfully disagree. Claim 22 is directed to "a method of treatment for secretory diarrhea in animals, including humans, said method comprising" and claim 36 is directed to "the method of claim 22, in which a non human animal is treated for secretory diarrhea." It is clear that independent claim 22 is directed to animals including humans, whereas claim 36 is limited to "non-human" animals and, thus, limits the subject matter of claim 22 to non-human animals only. In view of the foregoing, the withdrawal of objection to claim 36 under 37 CFR 1.75(c) is respectfully requested.

CONCLUSION

Applicants respectfully request that the present amendment and remarks be entered and made of record in the instant application. Claims 21-40, 75, and 76 fully meet all statutory requirements for patentability. Withdrawal of the Examiner's rejections and objection, and allowance and action for issuance are respectfully requested. Applicants respectfully request that the Examiner call the undersigned if any questions or issues remain.

Respectfully submitted,

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